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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/772,598      | 01/30/2001  | Timothy E. Benson    | 6315.N              | 2967             |

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EXAMINER

MAHATAN, CHANNING

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

DATE MAILED: 04/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/772,598

Applicant(s)

BENSON ET AL.

Examiner

Channing S. Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 1 Sheet 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *APPLICANTS' ARGUMENTS*

Applicants' arguments in Paper No. 11, filed 30 January 2003, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 35 and 38-43.

### **Claims Rejected Under 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 38 is rejected under 35 U.S.C. § 102(e) as being unpatentable over Kunsch et al. (Pub. No. US 2003/0054436).

Kunsch et al. discloses isolated *Staphylococcus aureus* polynucleotides and recombinant methods of producing the encoded proteins. (See pages 3-4; Summary of the Invention Section.) Table 2 at pages 42-43 discloses Contig ID Nos. 1192 and 32, as being *Staphylococcus aureus* homologs of NAD synthetase. It is noted that SEQ ID NO: 1 of the instant application has significant similarity to SEQ ID NO: 12 of Pub. No. US 2003/0054436. (See attached

Art Unit: 1631

alignment.) The reference teaches on page 10, paragraph [0144] that the proteins can be isolated by freeze-thaw cycling of microbial cells used for recombinant production. This would result in a crystal of the protein. Note that claim 38 does not require any particular type or quality of crystal and that the claim is not limited to a particular sequence.

It is noted that the specification states "NAD synthetase was expressed from recombinant *Escherichia coli* culture TU576 (M15 pQE60-NAD synthetase), an expression strain constructed by Human Genome Sciences" (page 38, lines 8-10 of the Specification).

### **Claims Rejected Under 35 U.S.C. § 103**

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

It should be noted that Hampton Research (Tel. No. 949-425-1321), contacted on 30 September 2002, indicated Crystal Screen™ was available for sale beginning 1991. Thus, the date of sale justifies the applicability of the above reference for the below 35 U.S.C. § 103 Rejections.

Claims 35 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Crystal Screen™ (Hampton Research) taken in view of Kunsch et al. (Pub. No. US 2003/0054436; Kunsch et al. is applied as above).

Crystal Screen™ is a complete reagent kit designed to provide rapid a screening method for the crystallization of biological molecules (i.e. proteins, etc) and allows for the determination of crystallization conditions (page 1, Column 1, lines 1-4). Procedures for performing the screen

Art Unit: 1631

and obtaining crystals is set forth (pages 1-2, beginning on Column 1, line 11). The attached Crystal Screen™ Scoring Sheet lists numerous solutions/conditions (6, 9-10, 13-15, etc.) for obtaining a crystal comprising a solution/conditions as claimed in instant claim 38. For example, solution/conditions of “No. 6” utilizes 30% PEG 4000, 0.1M Tris HCl pH 8.5, 0.2M Magnesium Chloride.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Crystal Screen™, determination of crystallization conditions for a biological molecule (i.e. protein) and obtaining a crystal of a biological molecule with Kunsch et al. (Pub. No. US 2003/0054436) *Staphylococcus aureus* NAD synthetase for further study and characterization of the protein and potential binding agents (i.e. drugs) (Kunsch et al. page 16, Screening Assay for Binding Agents section). Crystal Screen™ is also effective in determining the solubility of a molecule in a wide range of precipitants and pH (page 1, Column 1, lines 4-5).

#### *INFORMATION DISCLOSURE STATEMENT*

It is acknowledged that the Examiner only initialed the first listed document (erroneously) on one of the 1449 forms (Paper No. 4, filed 08 January 2002; page 3 of 5). For reasons of record all references listed were considered on 16 September 2002 as initialed at the bottom of the 1449. A copy of the said 1449 form is attached, wherein the error is corrected.

#### *OBJECTION TO DISCLOSURE*

The objection to the specification on pages 10-11, Tables 3-5, requiring line spacing correction is vacated. Applicants' amendment to the specification in Paper No. 11, filed 30 January 2003, with respect to Tables 3-5 was not entered. It should be noted that a mark up copy of Tables 3-5 was not received, however, said objection is now vacated and found moot.

Art Unit: 1631

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *April 4, 2003*

Examiner Initials: *CSM*

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1800  
*4/16/03*